

AMENDMENTS TO THE CLAIMS

1. (currently amended) An apparatus for treatment of cerebral aneurysms and AVMs, comprising:

a laser generating ultraviolet radiation;

a steerable guide wire ~~including~~ housing an optical fiber including proximal and distal fiber ends, said fiber ~~extended~~ extending from the proximal to the distal end of the guide wire and coupled at said proximal fiber end to the laser, such optical fiber providing a transmissive pathway for the laser-generated ultraviolet radiation to said optical fiber distal end for emission therefrom, and;

an over-the-wire catheter including proximal and distal catheter ends and further including having an occlusive balloon and a micro tube adapted for delivery of saline into an artery distally to the ~~balloon catheter distal end~~ for displacing blood from the aneurysm or AVM and clearing the optical field in front of the distal end of the optical fiber, said guide wire being slidable received within said catheter and being reciprocably movable therein such that said optical fiber distal end can be extended beyond said catheter distal end such that said ultraviolet radiation emitting optical fiber distal end is not obstructed by said catheter;

wherein said apparatus delivers ultraviolet radiation to the inside surface of the aneurysm or AVM so as to cause the death of a sufficient number of the endothelial cells on the

irradiated surface of the aneurysm such that a mural thrombus is formed and the aneurysm is strengthened against rupture.

2. (Currently amended) The apparatus of claim 1 wherein the laser generates [UV] ultraviolet radiation in the range of 240 to 280 nanometers, corresponding to maximum [UV] ultraviolet absorption in DNA.
3. (Currently amended) The apparatus of claim 1 wherein said fiber distal end is coupled to an optical tip adapted for scattering [UV] ultraviolet radiation in ~~different~~ substantially semispherical directions for substantially complete irradiation of the inner surface of the aneurysm.
4. (Currently amended) An apparatus for treatment of aneurysms comprising:
 - a laser generating ultraviolet radiation;
 - a steerable guide wire including proximal and distal wire ends;
 - an over-the-wire catheter including a wall and at least one optical fiber including proximal and distal fiber ends ~~inside~~ disposed within said catheter wall, wherein said proximal fiber end is coupled to the laser and said distal fiber end is extended to said distal end of said catheter, said catheter including a central passage for ~~adapted for receiving said guide wire and for~~ delivery of saline into an artery for displacing blood from the aneurysm or AVM and clearing the optical field in front of the distal end of the optical fiber;

wherein said apparatus delivers ultraviolet radiation to the inside surface of the aneurysm so as to cause the death of a sufficient number of the endothelial cells on the irradiated surface of the aneurysm such that a mural thrombus is formed and the aneurysm is strengthened against rupture.

5. (Currently amended) The apparatus of claim 4, in which the laser generates [UV] ultraviolet radiation in the range of 240 to 280 nanometers, corresponding to maximum [UV] ultraviolet absorption in DNA.

6. (Currently amended) The apparatus of claim 4 and including a plurality of optical fibers each including proximal and distal fiber ends, wherein at least one of said distal fiber ends is coupled to an optical tip adapted for scattering [UV] ultraviolet radiation in ~~different~~ substantially semispherical directions for substantially complete irradiation of the inner surface of the aneurysm.

Claims 7-21 (Cancelled)

REMARKS

Claims 1-6 are now pending in this case. To further the prosecution of this case, Applicants have amended pending claims 1-6, and have canceled previously pending claims 9-18

General Remarks

The applied prior art of U.S. Patent No. 5,620,438 to Amplatz et al. and U.S. Patent No. 4,512,762 to Spears are directed to methods and apparatus for the treatment of atherosclerosis and not aneurysms or AVMs as is Applicants' invention. At least one purpose of both patents is to prevent tissue growth or to kill tissue within the blood vessel. Amplatz et al. states that illumination of a previously dilated segment of artery wall (through angioplasty) will kill smooth muscles cells that would otherwise proliferate following the angioplasty, leading to a thickening of the artery wall and thus restenosis of the artery. (Col. 4, ll.56-58). Spears teaches illumination of atheromatous plaque tissue to activate previously injected hematoporphyrin that has been selectively absorbed by the plaque to kill the plaque and thus open the artery. (Col. 1, ll. 35-42)

Applicants' invention, to the contrary, is directed to method and apparatus to create or encourage tissue growth within an aneurysm or AVM for the purpose of preventing ruptures thereof. As such, Applicants submit that one skilled in the art of creating or encourage tissue growth would not look to either Amplatz or Spears and that neither patent contains any suggestion that the teachings therein could be used individually or collectively for the treatment of aneurysms or AVMS.

Claims 1-3

Applicants traverse the rejection of claims 1- 2 as anticipated by Amplatz et al. and claim 3 as being unpatentable over Amplatz et al. in view of Spears. To further the prosecution of this case, however, Applicants have amended claim 1.

As amended claim 1 recites that the apparatus includes a tube for the delivery of saline into the artery distally of the end of the balloon. Neither Amplatz et al. or Spears discloses any structure for intentional intra-arterial saline delivery to clear a visual field distal of the end of the catheter.. Amplatz et al. uses a fluid to inflate a balloon within an artery, as does Spears in one embodiment, but neither teaches apparatus for or delivery of saline distally of the end of a catheter for clearing of a visual field for application of the UV radiation. Amplatz et al. does state that saline flow prevents blood from entering into the distal end of their catheter, (Col 3., l. 66 – Col. 4, l. 2); however, the visual field in Amplatz et al. is within the balloon 18.

As amended claim 1 also recites that the guide wire houses the optical fiber. Applicants submit that Amplatz et al. does not disclose the use of a guide wire. Amplatz et al. states that it includes “an outer tubular reinforcing member 54” that “tightly surrounds the jacket 46 of the quartz fiber 44”. (Col. 4, ll. 18-22) In addition, it is noted that the member 54 terminates approximately 13 inches prior to the end of the fiber. (Col. 4, ll. 27-29). Thus, Applicants submit that no guide wire and particularly no steerable guide wire as known in the art that houses the fiber substantially along its entire length is disclosed by Amplatz et al. Certainly no steering function is provided or claimed by Amplatz et al. Nor does the Amplatz et al. “reinforcing member” extend

substantially along the entire length of the fiber as Applicants' recited steerable guide wire does.

Spears discloses a guide wire 28 housed within the hollow glass fiber 24. It thus teaches a structure directly opposite to that recited by Applicants in claim 1 – “a steerable guide wire ~~including~~ housing an optical fiber”

Furthermore, as shown in Figures 6A-C and 7, aneurysms oftentimes are formed at substantial angles to the wall of the artery. The use of a guide wire extending to the tip of the optical fiber is thus necessary to enable the treating physician to steer the optical tip into the proximity of the aneurysm wall as shown in Figure 1 in order to be able to irradiate it. Amplatz et al. does not teach the use of such a steerable guide wire since the fiber is “naked” other than a Teflon coating over the last 13 inches of its length.

Applicants have amended claim 3 to recite that its optical tip radiates substantially semispherically so as to irradiate forward and side directions of an aneurysm or AVM such as shown in Figures 1 and 3. Amplatz et al. and Spears include radiators designed to radiate substantially radially along the length of their radiators. This is desirable for their applications since they intend to irradiate the length of the artery wall along their radiators and have no necessity – or probably any desirability – to radiate in a forward direction. In fact, Amplatz et al. specifically teaches the use of a radio-opaque plug 52, ostensibly to prevent substantial forward direction radiation transmission. Spears is silent on this point; however, since as shown in Figure 1 thereof that the use of the Spears apparatus is to transmit radiation into a longitudinally extending segment of arterial wall, it seems unlikely that its radiator would be designed for forward transmission into a normal segment of arterial wall. Applicants, however, do seek to radiate in forward as

well as side directions so as to be able to irradiate the curving surface of an aneurysm or AVM and thus have recited on optical tip for such a purpose.

For all of the foregoing remarks Applicants submit that claims 1-3 are allowable over the applied art of Amplatz et al. and Spears, taken individually or collectively.

Claims 4-6

Claims 4-5 stand rejected as anticipated by Amplatz et al and claim 6 stands rejected as being unpatentable over Amplatz et al. in view of Spears. To further the prosecution of this case, however, Applicants have amended claim 4-6.

As amended claim 4 clarifies that the optical fiber(s) is disposed within the catheter wall and that the catheter delivers saline into the artery. Neither Amplatz et al. or Spears teaches a catheter with one or more optical fibers disposed within the wall and which delivers saline distally of the end of the catheter into the artery.

Applicants submit that Amplatz et al. teaches a catheter having multiple lumen passages 14 and 16 for fluid delivery for reciprocal movement of its optical fiber, respectively. As shown in Applicants Figure 4, the distal end of the apparatus may be inserted within the neck of the aneurysm 60, thus reciprocal movement of the fibers 32 is unnecessary with respect to Applicants invention.

As noted above, as shown in Figures 6A-C and 7, aneurysms oftentimes are formed at substantial angles to the wall of the artery. The use of a guide wire extending substantially to the tip of the optical fiber is thus necessary to enable the treating physician to steer the optical tip into the proximity of the aneurysm wall as shown in Figure 1 and 4 in order to be able to irradiate it. Amplatz et al. does not teach the use of

such a steerable guide wire since the fiber is "naked" other than a Teflon coating over the last 13 inches of its length.

Applicants have amended claim 6 to recite that its optical tip radiates substantially semispherically so as to irradiate forward and side directions of an aneurysm or AVM such as shown in Figures 1 and 3. Amplatz et al. and Spears include radiators designed to radiate substantially radially along the length of their radiators. This is desirable for their applications since they intend to irradiate the length of the artery wall along their radiators and have no necessity – or probably any desirability – to radiate in a forward direction. In fact, Amplatz et al. specifically teaches the use of a radio-opaque plug 52, ostensibly to prevent substantial forward direction radiation transmission. Spears is silent on this point; however, since as shown in Figure 1 thereof that the use of the Spears apparatus is to transmit radiation into a longitudinally extending segment of arterial wall, it seems unlikely that its radiator would be designed for forward transmission into a normal segment of arterial wall. Applicants, however, do seek to radiate in forward as well as side directions so as to be able to irradiate the curving surface of an aneurysm or AVM and thus have recited on optical tip for such a purpose.

For all of the foregoing remarks Applicants submit that claims 4-6 are allowable over the applied art of Amplatz et al. and Spears, taken individually or collectively.

Petition for Extension of Time

The three month response date for responding to the Office action of February 28, 2006 was May 28, 2006. Applicants hereby petition for a two month extension of time to make this response timely. Applicant's authorize the Office to charge Deposit Account